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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/449,093	11/24/99	HARTAL	D 4118

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EXAMINER
SHERRER, C

ART UNIT	PAPER NUMBER
1761	14

DATE MAILED: 06/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/449,093

Applicant(s)

Hartal et al

Examiner

Curtis E. Sherrer

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 17, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 23-44 is/are pending in the application.
- 4a) Of the above, claim(s) 29-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 23-28, and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13 20) ☐ Other:

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Part III DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-14, 23-28 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

2. Applicants have amended their claims to recite the amount (by weight) in ppm of chromoplasts and basis for this amendment was not found.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-14, 23-28 and 41-48 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Applicants state that processing steps are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

5. Applicants cite to their specification whereby it states "conventional methods of extraction destroy the crystalline structure of this pigment." They state that a "key aspect of the present invention therefor is to liberate the chromoplast from the fruit without causing substantial mechanical breakage or destruction of the chromoplast." Page 9 of Paper #9, After Final

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Amendment). A review of the specification discloses that the processing of tomatoes to produce the instant product (except for the centrifugation) is "not essentially different [than] those conventionally carried out in the tomato processing industry." It is therefore unclear, at present, what process conditions (extraction steps) are being relied on to keep the chromoplast particles intact.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-14, 23-28 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1, 8, 25 and 41 are indefinite because the scope of the term "substantially" is unknown. Claim 41 is indefinite because the scope of the term "partially" is unknown. The phrases are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

9. Claim 4 is indefinite because the scope of the term "flavor" is unknown.

10. Claim 5 is indefinite because the scope of the phrase "high lycopene content tomato" is unknown.

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11. Claim 10 is indefinite because the scope of the phrase "water soluble flavors" is unknown.
12. Claim 12 is indefinite because the use of the phrase "such as" it is not clear if the following techniques are positive limitations.
13. Claim 25 is indefinite because the scope of the phrase "tomato flavor" is unknown.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

15. Claims 1-14, 23-25 and 28 to are rejected under 35 U.S.C. § 102(b)/102(e) as being anticipated by Graves et al (USPN 5,245,095).
16. Graves et al teach the production of a carotenoid extract. This involves fractionation of "any carotenoid natural source . . . such as . . . tomatoes" (col. 2, line 64 to col. 3, line 1). The fractionation is performed by first separating "the natural source into a carotenoid-containing liquid fraction and a pulp fraction", which can be performed by simply juicing the carotenoid source and filtering the juice through a course-mesh filter." (Col. 3, lines 8 to 16). Fractionation then occurs through precipitation of the carotenoid material and then separation of the precipitate

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can be "achieved by any conventional method, including centrifugation/decantation/freeze drying", etc., (Col. 4, lines 51 to 56). Further processing can be performed to further refine concentrated carotenoid, such as chemical hydrolysis "whereby the noncarotenoid constituents are rendered separable from the carotenoid(s) in an aqueous media." (Col. 2, lines 18 to 30).

17. The product can then be used as a pigment. (Col. 4, lines 57 to 60). The patent teaches that "[c]arotenoids, . . . , are valuable pigments useful for coloring various comestibles, such as margarine" (col. 1, lines 31 to 36). In the previous paragraph, the patentees mention that lycopene is the common carotenoid responsible for the color in tomatoes.

18. It is considered that the product described and produced by the patented method of Graves et al is inherently the same as that now claimed. The Office does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed products. In the absence of evidence to the contrary, the burden is upon the applicants to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 1977); *Ex parte Gray*, 10 U.S.P.Q.2d 1922, 1923 (BPAI).

19. Graves et al is being applied as a 102(b) reference on those claims that recite centrifugation because the priority applications contain no disclosure of centrifugation. Otherwise, it is applied as a 102(e) reference.

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20. Claims 14, and 41-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by ~~Tannic~~^{Tonnucci} et al (Jnl. of Agricultural and Food Chemistry).

21. ~~Tannic~~^{Tonnucci} et al teach that which is inherent in tomato based products. Specifically, the data presented by ~~Tannic~~^{Tonnucci} et al, found in Table 3, show that tomato paste has a lycopene content of around 550 ppm. This is higher than the amount claimed for the coloring material. The paste sample was obtained from "name-brand and store-brand tomato-based thermally processed foods" (page 580, col. 1). The article cites several authors who have discovered the antioxidant properties of lycopene (see Introduction). Further, Di Maresco et al, is cited as discovering, in 1990, that "lycopene is the most efficient quencher of singlet oxygen which makes its presence int he diet of considerable interest".

22. Claims 1-3, 5 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Iwatsuki et al. (Plant Cell Physiology, Abstract).

23. Iwatsuki et al. teach the isolation of tomato chromoplast fractions and recorded an increase in the inherently contained lycopene. Further, the chromoplasts contained "mitochondria and other microbodies", which are considered to be "color-neutral substances."

24. As to the limitation of Claim 5, i.e., "the tomato is a high lycopene-content tomato", it is considered that the product, i.e., lycopene in chromoplasts from *Lycopersicon esculentum* Mill

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cv. First (which may be a high lycopene-content tomato), is indistinguishable from lycopene in chromoplasts from high lycopene-content tomatoes.

25. Claims 8, 9 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dale et al. (Jnl. of Food Sci.).

26. Dale et al. teach the processing of tomatoes where they are "washed, sorted, and then chopped into steam jacketed vessels and heated to 90°C. The skin and seeds were then removed using a 0.0114 cm separator. The warm tomato pulp was then pumped, using positive displacement pump, into a . . . bowl [and then into a] continuous centrifuge" It is considered that due to the concentration of the pulp the increase in acidity will aid in "avoiding degradation by microbial spoilage."

27. Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brumlick et al. (U.S. Pat. No. 4,181,743).

28. Brumlick et al. disclose food flavorings and methods for their production. Example III discloses "pressed tomato juice containing the red coloring matter is boiled down or freeze dried."

The products are "used for flavoring a variety of foods or as a low sodium salt substitute which may be spread by hand or from a container across food about to be eaten or mixed with foods to enhance their taste." (Col. 1, lines 45 to 49). While the patent discusses the products in

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connection with flavoring foods, the product of Example III inherently will add color, as contemplated by Applicants, to the target food. It is also considered inherent, without a showing to the contrary, that the product of Example III has chromoplasts that contain crystalline lycopene.

29. Claims 1-3, 5, 6, 13, and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Szabo et al. (U.S. Pat. No. 3,864,504)

30. Szabo et al. teach a process to produce high concentration tomato puree by transforming colloids whereby tomatoes are triturated (i.e., comminuted) "in order to remove skin and seed parts, and partly to get a liquid consistence [and] easier to handle" The serum is then separated and the "red colored fraction of colloids is very little hygroscopic. With relatively little energy a 20-30 percent water content can be obtained {by} . . . centrifuge" and this fraction is can then be added back to the previously separated serum (a tomato product).

31. Again, it is also considered inherent, without a showing to the contrary, that the product of the cited patent has chromoplasts that contain crystalline lycopene.

32. Claims 1-5 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bradley (U.S. Pat. No. 4,670,281).

33. Bradley teaches the processing of tomatoes whereby tomatoes are macerated and subjected to a relatively mild (with respect to the prior art) centrifugal step to remove the liquid content and

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then the skins and seeds are removed. The final product of this process can be used in various products. (See patent disclosure).

34. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

35. Claims 1-5, 7 and 13 and 14 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lang (U.S. Pat. No. 5,229,160).

36. Lang teaches a process for producing three tomato fractions produced by macerating the tomatoes and essentially washing with water the macerated tomatoes in a counter-current extractor. The "liquid portion or serum contains a large proportion of the aroma and flavor components of the tomatoes." The solids phase, after the skins and seeds have been removed and it has been dewatered "contains a high proportion of the viscosity inducing ingredients of the tomato and most of its color." (See generally col. 3, lines 17 to 57). "These fraction may be recombined in any combination allowing total flexibility when formulating pastes, juices or sauces." "The quality and stability of the color of the tomato products from the present process is significantly better that achieved by tradition procedures." (See col. 3, lines 59 to 68).

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Claim Rejections - 35 USC § 103

37. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

38. Claims 26 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Graves et al. in view of Horn et al (U.S. Pat. No. 4,726,955).

39. Graves et al teach that cited above but do not disclose the further size reduction of the concentrated carotenoids.

40. Horn et al teach the prior use of a colloid mill to reduce the size of carotenoids to increase their solubility. (Col. 1, lines 31 to 45). It would have been obvious to those of ordinary skill in the art to use the colloid mill of the prior art, as taught by Horn et al, in the process of Graves et al for it intended and well taught use.

41. Claims 1-5, 7, 13 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lang in view of Brumlick et al.

42. Lang teaches that which is cited above but does not mention (1)the cleaning of the tomatoes before macerating or (2)the freezing or dehydrating the final product of the process.

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43. It is considered that the cleaning, freezing and dehydrating of tomatoes are such standard and commonly practiced process steps in the tomato processing industry that it would be obvious to one of ordinary skill in the art.

44. Nevertheless, Brumlick et al. teaches that cited above, i.e., freeze drying of the final tomato product.

45. It would have been obvious to one of ordinary skill in the art to freeze dry the tomato product of Lang as done by Brumlick et al. since freeze drying has the well known benefits of reducing the weight and increasing shelf life of food products.

46. It would have been obvious to one of ordinary skill in the art to preclean the tomatoes of Lang since consumers demand clean, pure and safe food products.

47. Claims 1-14 and 24-28 are rejected under 35 U.S.C. § 103 as being unpatentable ^{Tonnucci} ~~Tannic~~ et al (Jnl. of Agricultural and Food Chemistry) in view of Dale et al. (Jnl. of Food Sci).

48. ^{Tonnucci} ~~Tannic~~ et al teach that cited above. Specifically, they teach the importance of using lycopene as an antioxidant. They do not teach a coloring product that has 1000 ppm of lycopene but it would be obvious to one of ordinary skill in the art to make and to use a product that has as much lycopene as possible so as to maximize the antioxidant effects. Further, it would be obvious to one of ordinary skill in the art to use a lycopene product in conjunction with foods.

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49. The claimed process steps in producing a tomato product, such as tomato paste, are all conventional and well known in the art, as evidenced by the other cited prior art. It is well known to clean tomatoes to remove mud and debris before they are processed. It is known to remove the seeds and to centrifuge the serum. This much is taught by Dale et al. It would be obvious to use lycopene containing products such as tomato paste in conjunction with foods for the antioxidant effect of the lycopene. As stated below, an application, e.g. coloring, of an old process is not patentable.

Response to Arguments

50. Applicants' arguments filed 04/11/01 and 03/30/01 have been fully considered but they are not persuasive.

51. Applicants argue that the cited art do not anticipate the claims because they do not teach that they are substantially intact or intact. See comments above under the 112 first paragraph rejection. For the purposes of the prior art rejection, Applicants' comment that conventionally used methods of processing tomatoes is appropriate for making the instant product. Therefore, the rejections are maintained.

52. The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the

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absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed are functionally different than those taught by the prior art and to establish patentable differences. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 1977); *Ex parte Gray*, 10 U.S.P.Q.2d 1922, 1923 (BPAI).

53. Applicants cite to their specification whereby it states "conventional methods of extraction destroy the crystalline structure of this pigment." They state that a "key aspect of the present invention therefor is to liberate the chromoplast from the fruit without causing substantial mechanical breakage or destruction of the chromoplast." Page 9 of Paper #9, After Final Amendment). A review of the specification discloses that the processing of tomatoes to produce the instant product (except for the centrifugation) is "not essentially different [than] those conventionally carried out in the tomato processing industry." It is therefore unclear, at present, what process conditions (extraction steps) are being relied on to keep the chromoplast particles intact.

54. With regard to Applicants arguments directed to the rejection based on Graves et al, Applicants equate said patent's statement concerning "cell disruption" to the "destruction of the chromoplast membrane" and no basis for this comparison is presented. It is respectfully considered that Applicants also disrupt the "cells" in order to release the chromoplasts for further processing. The anticipation rejection is maintained because said patent teaches the use of Applicants' process and therefore inherently teaches the claimed product. Again see *In re Best*.

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55. With regard to Applicants arguments directed to the rejection based on Iwatsuki, Applicants state that the disclosure is directed only to chromoplasts that are devoid of lycopene. Applicants have provided no basis for such an assertion. While Iwatsuki states that the chromoplasts are isolated, nothing infers that the lycopene contained within the chromoplasts were extracted before isolation.

56. With regard to Applicants arguments directed to the rejection based on Tonucci and the remaining cited art, Applicants assert that their disclosures are covered by Applicants statements found in the instant specification, whereby the pastes and concentrates contain other components, such as soluble solids, flavor, and aromas that would have Brix values outside of the claimed value. While this may be true of pastes and concentrates, it is not true for juices. It is well known that tomato juices will have Brix values of around 5, even less than 5.

57. It is noted that the claims rejected under 102 by Tonucci are drawn to products using the claimed coloring products and it is considered that the prior art products anticipate these claims because the use of the claimed coloring agent is a process limitation and therefore it is given no patentable weight.

58. With regard to Bradley, Applicants express their opinion that the membrane of chromoplasts would be broken but provide no evidence to support their opinion.

59. With regard to the other prior art, Applicants state that the heat "will inevitable disrupt the membrane and release the lycopene." No hard evidence is given to support Applicants' opinion.

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Nothing in the specification supports this opinion evidence and it is considered that if processing temperature is critical it should be disclosed and claimed.

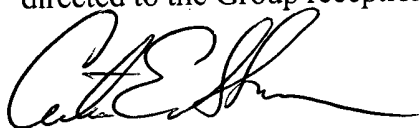
Conclusion

60. No claim is allowed.

61. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kwaragi et al. (U.S. Pat. 5,871,574) teach a method for collectin tomato pigment.

62. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Curtis Sherrer whose telephone number is (703) 308-3847. The examiner can normally be reached on Tuesday through Friday from 6:30 to 4:30. The fax phone number for this Group is (703)-305-3602.

63. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



Curtis E. Sherrer
Primary Examiner
June 21, 2001